

CONDITIONAL PETITION FOR EXTENSION OF TIME

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefor. The Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the amendments above and the following comments.

At the outset, Applicants acknowledge with appreciation the substantial progress in this application in that numerous previous rejections have been withdrawn.

The sole remaining issue is the rejection of claims 9, 11, 29, 30, 35 and 37 under 35 USC § 102 (a and e) as being anticipated by Barrat et al. (“Barrat”), US 2002/0090357, as evidenced by Fujimaki et al. (“Fujimaki”), *Clin. Develop. Immunol.*, pp. 1-12 (2008). In response, Applicants have amended claim 9 above to incorporate the substance of claims 37 and 38; and to separate the activation and anergizing steps. Further, Applicants have required that the activation stimulus “consists” of either (a) plate-bound anti-CD3 and soluble anti-CD28 antibodies or (b) mature dendritic cells.

Applicants would remind the Examiner that anticipation requires that each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference, and, further, the absence in the prior art reference of even a single one of the claim elements is sufficient to negate anticipation. *In re Robertson*, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

Applicants respectfully submit that Barrat does not teach an activation stimulus consisting of either (a) plate-bound anti-CD3 and soluble anti-CD28 antibodies or (b) mature dendritic cells, as required by the instant claims. Consequently, Barrat cannot anticipate the present claims, even as evidenced by Fujimaki.

Further on this point, Applicants point out that Barrat is directed to the production of (alleged) regulatory T cells and emphasizes throughout the importance of “contacting a naïve T cell with a stimulatory signal and an appropriate amount of a combination of Vitamin D3 and Dexamethasone....” See, for example, Barrat at paragraph [0007]. Thus, Barrat’s activation stimulus, contrary to the present claims, requires not only a stimulatory signal, which can be APC or anti-CD3 and anti-CD28, but also the combination of D3 and dexamethasone, which are excluded from the present claims by the “consisting of” language.

The instant examples, beginning on page 13 of the instant specification, demonstrate that activation of CD4⁺ CD25⁺ T cells by stimulation with an activation stimulus consisting of either (a) plate-bound anti-CD3 and soluble anti-CD28 antibodies or (b) mature dendritic cells gives rise to a population of CD4⁺ CD25⁺ T cells that is capable of anergizing CD4⁺ CD25⁻ T cells in a contact-dependent manner. For instance, in Example 2, isolated CD4⁺ CD25⁺ T cells were activated by stimulation with an activation stimulus consisting of plate-bound anti-CD3 and soluble anti-CD28 antibodies. The activated CD4⁺ CD25⁺ T cells were then mixed with syngeneic CD4⁺ CD25⁻ T cells resulting in anergized CD4⁺ CD25⁻ T cells. As shown in Figure 2A, and as discussed at the top of page 14 of the specification, the activated CD4⁺ CD25⁺ T cells “almost completely suppressed proliferation of CD4⁺ CD25⁻ T cells when a 1:1 ratio was used.”

As shown in Example 4, for instance, the anergized CD4⁺ CD25⁻ T cells were capable of suppressing the activation of syngeneic CD4⁺ T cells in an IL-dependent manner.

In view of the foregoing, Applicants respectfully submit that the method of the present claims is distinguished from Barrat's method and, therefore, Barrat does not anticipate the present claims, even as evidenced by Fujimaki. An early notice to that effect is earnestly solicited.

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,
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